CLAIMS

1. A method of producing particles from a feedstock material, as hereinbefore defined, for the use in the delivery of drugs by inhalation, whereby at least one particle attribute, selected from the group consisting of morphology, topography or aerodynamic diameter, is engineered to fit the needs of a selected patient type, said method comprising the steps of:

a) providing a mimicked respiratory system, which is adapted to simulate at least one of the drug delivery target regions of the mammalian respiratory system;

b) providing an engineering medium within the mimicked respiratory system at a controlled temperature to create an environment that is conducive to the production of engineered particles, said medium comprising at least one gas;

c) operating the mimicked respiratory system to simulate a controlled inhalation flow rate within the system for a set period of time, whereby a controlled inhalation power is imparted on the mimicked respiratory system;

d) providing an aerosolised feedstock material within the mimicked respiratory system, whereby the type of engineered particles produced in the reaction of the feedstock material with the engineering medium is dictated by the controlled inhalation power;

e) collecting the resultant engineered particles from at least one of the simulated drug delivery target regions provided by the mimicked respiratory system.

2. The method of claim 1, wherein the mimicked respiratory system is provided by a modified twin stage impinger as hereinbefore defined, an Andersen cascade impactor, or any other device capable of simulating at least one drug delivery target region of the mammalian respiratory system as hereinbefore defined.

3. The method of claim 1 or 2, wherein the drug delivery target regions simulated by the mimicked respiratory system are selected from the group

containing: naso-pharynx; oropharynx; trachea; bronchi; bronchioles; alveolar ducts; and alveolar sacs.

4. The method of claims to 1, 2 or 3, wherein the inhalation flow rate within the mimicked respiratory system is between 1 and 1000L/min.

5. The method of claim 4, wherein the inhalation flow rate within the mimicked respiratory system is set at a rate which simulates a natural inhalation flow rate of a mammalian lung, which is between 15 and 120L/min.

6. The method of claims 1 to 5, wherein the feedstock material comprises at least one of the following constituents:

i) a therapeutic, prophylactic, or diagnostic substance;
ii) a liquid;
iii) an excipient; and
iv) a base and/or an acid.

7. The method of any of the preceding claims, wherein the feedstock material is spayed into the mimicked respiratory system to provide the aerosolised feedstock material within the mimicked respiratory system.

8. The method of any of the preceding claims, wherein the feedstock material is sucked into the mimicked respiratory system to provide the aerosolised feedstock material within the mimicked respiratory system.

9. The method of claim 8, wherein the inhalation flow rate within the mimicked respiratory system provides the suction to draw the feedstock material into the mimicked respiratory system.

10. The method of any of the preceding claims, wherein the feedstock material comprises at least one therapeutic substance selected from a group containing: corticosteroids; anti-inflammatories; anti-tussives; bronchodilators; and proteins.

11. The method of any of the preceding claims, wherein the feedstock material comprises at least one therapeutic substance selected from a group containing: beclomethasone diproprionate; budesonide; fluticasone propionate; salmeterol xinofoate; salbutamol sulphate; and bovine serum albumin.

12. The method of any of the preceding claims, wherein the feedstock material comprises at least one excipient selected from a group containing: monosaccharides; disaccharides; polysaccharides; and sugar alcohols.

13. The method of any of the preceding claims, wherein the feedstock material is passed through a filter before entering the mimicked respiratory system to control the size of the aerosolised feedstock material particles.

14. The method of claim 13, wherein the feedstock material is filtered to permit only particles having a diameter of 100μm or less to enter the mimicked respiratory system.

15. The method of any of the preceding claims, comprising the further step of pre-treating the feedstock before it is introduced into the mimicked respiratory system.

16. The method of claim 15, wherein the pre-treatment step involves subjecting the feedstock to at least one liquefied gas.

17. The method of any of the preceding claims, wherein the engineering medium further comprises at least one fluid selected from a group containing: water; a ketone; an alcohol; a fluorocarbon; a fluoroalkane; an acid; a base; a liquefied gas; or combinations thereof.

18. The method of claim 17, wherein the at least one fluid is selected from a group containing: water; acetone; ethanol; hydrofluoroalkanes; chlorofluorocarbons; and liquid nitrogen.

19. The method of claim 17 or 18, wherein the step of providing an environment within the mimicked respiratory system further comprises agitating the engineering medium by directing the controlled inhalation flow through the at least one liquid present in the mimicked respiratory system.

20. The method of any of the preceding claims wherein the inhalation flow gas is selected from a group consisting of: air; nitrogen; oxygen; carbon dioxide; helium; argon; and combinations thereof.

21. The method of any of the preceding claims, wherein the temperature in the mimicked respiratory system is controlled at a temperature of between -200 and 200°C.

22. The method of any of the preceding claims, wherein the temperature is maintained at between -50 and 120°C.

23. The method of any of the preceding claims, wherein the temperature is maintained at a level which simulates that of the mammalian lungs, which is between 34 and 42°C.

24. The method of any of the preceding claims, wherein the engineering medium contains at least one substance that is capable of evolving a gas when combined with another substance in an effervescent reaction.

25. The method of any of the preceding claims, wherein the feedstock material contains at least one substance capable of evolving a gas when combined with another substance in an effervescent reaction.

26. The method of any of claims 24 or 25, wherein carbon dioxide is evolved by the combination of a base and an acid in an effervescent reaction.

27. The method of any of the preceding claims, wherein the mimicked respiratory system further comprises at least one spacer device as hereinbefore defined.

28. The method of claim 27, wherein the at least one spacer device is provided in the mimicked respiratory system at a point between where the feedstock material is introduced into the mimicked respiratory system and the point where at least one of the simulated drug delivery target regions are provided by the mimicked respiratory system.

29. The method of claim 27 or 28, further comprising the step of creating a local environment within each spacer device that is distinct from that within the rest of the mimicked respiratory system.

30. The method of claim 27, 28 or 29, wherein each provided spacer device comprises at least one inlet and at least one outlet, whereby the introduction of an engineering medium is used to control the internal environment of each spacer device.

31. The method of any of the preceding claims, further comprising the step of analysing the particles deposited at the one or more simulated drug delivery target regions provided by the mimicked respiratory system, and using the results collected to provide feedback on a particular particle engineering environment.

32. An engineered particle obtained using a method according to any of claims 1 to 31.

33. An engineered particle according to claim 32, wherein the particle comprises at least one therapeutic agent selected from a group containing: beclomethasone diproprionate; budesonide; fluticasone propionate; salmeterol xinofoate; salbutamol sulphate; and bovine serum albumin.

34. An engineered particle according to claim 32, wherein the particle comprises lactose monohydrate.

35. A method of producing particles for the use in the delivery of drugs by inhalation, whereby the attributes of the particles are engineered to fit the needs of a selected patient type, substantially as described, with reference to the drawings, herein.